Complete Summary

GUIDELINE TITLE

Diagnosis and classification of diabetes mellitus.

BIBLIOGRAPHIC SOURCE(S)

Diagnosis and classification of diabetes mellitus. Diabetes Care 2004 Jan;27(Suppl 1):S5-S10. [4 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Diabetes mellitus including:

- Type 1 diabetes
- Type 2 diabetes
- Other specific types of diabetes (e.g., due to other causes) including:
  - genetic defects in beta-cell function
  - genetic defects in insulin action
  - diseases of the exocrine pancreas
  - endocrinopathies
  - drug or chemical induced
  - infection-related
  - uncommon forms of immune-mediated diabetes (e.g., "Stiff man" syndrome, anti-insulin receptor antibodies)
  - Other genetic syndromes sometimes associated with diabetes including:
    - Down's syndrome
    - Klinefelter's syndrome
    - Turner's syndrome
    - Wolfram's syndrome
    - Friedreich's ataxia

        - Huntington's chorea
        - Laurence-Moon-Biedl syndrome
        - Myotonic dystrophy
        - Porphyria
        - Prader-Willi syndrome
- Gestational diabetes mellitus

GUIDELINE CATEGORY

Diagnosis
Screening

CLINICAL SPECIALTY

Endocrinology
Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide appropriate recommendations for the diagnosis and classification of diabetes mellitus

TARGET POPULATION

Screening

- Individuals at risk of developing diabetes mellitus
- Pregnant women

Diagnosis

- Individuals with type 1 diabetes mellitus
- Individuals with type 2 diabetes mellitus
- Individuals with other specific types of diabetes
- Pregnant women with gestational diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

1. Assess for symptoms (e.g., polyuria, polydipsia, and unexplained weight loss)
2. Specialized risk assessment for pregnant women
3. Glucose testing:
    - Casual plasma glucose test
    - Fasting plasma glucose test
    - Oral glucose tolerance test
    - Glucose challenge test

MAJOR OUTCOMES CONSIDERED

Glucose levels

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations were reviewed and approved by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Details for definition, description, and classification of diabetes mellitus and other categories of glucose regulation can be found in the original guideline.

Diagnostic Criteria for Diabetes Mellitus

Three ways to diagnose diabetes are possible (see below), and each, in the absence of unequivocal hyperglycemia, must be confirmed, on a subsequent day, by any one of the three methods. The use of the hemoglobin A1c (A1C) for the diagnosis of diabetes is not recommended at this time.

The criteria for the diagnosis of diabetes are:

1. Symptoms of diabetes plus casual plasma glucose concentration $\geq$200 mg/dL (11.1 mmol/L). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.

   OR

2. Fasting plasma glucose (FPG) $\geq$126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h.

   OR

3. 2-h postload glucose ≥200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test (OGTT). The test should be performed as described by the World Health Organization (WHO), using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.

In the absence of unequivocal hyperglycemia, these criteria should be confirmed by repeat testing on a different day. The third measure (OGTT) is not recommended for routine clinical use.

Diagnosis of gestational diabetes mellitus (GDM)

The criteria for abnormal glucose tolerance in pregnancy are those of Carpenter and Coustan (1982). Recommendations from the American Diabetes Association´s Fourth International Workshop-Conference on Gestational Diabetes Mellitus held in March 1997 support the use of the Carpenter/Coustan diagnostic criteria as well as the alternative use of a diagnostic 75-g 2-h OGTT. These criteria are summarized below.

Testing for gestational diabetes.

Previous recommendations included screening for GDM performed in all pregnancies. However, there are certain factors that place women at lower risk for the development of glucose intolerance during pregnancy, and it is likely not cost-effective to screen such patients. Pregnant women who fulfill all of these criteria need not be screened for GDM.

This low-risk group comprises women who

- are <25 years of age
- are a normal body weight
- have no family history (i.e., first-degree relative) of diabetes
- have no history of abnormal glucose metabolism
- have no history of poor obstetric outcome
- are not members of an ethnic/racial group with a high prevalence of diabetes (e.g., Hispanic American, Native American, Asian American, African American, Pacific Islander)

Risk assessment for GDM should be undertaken at the first prenatal visit. Women with clinical characteristics consistent with a high risk of GDM (marked obesity, personal history of GDM, glycosuria, or a strong family history of diabetes) should undergo glucose testing (see below) as soon as feasible. If they are found not to have GDM at that initial screening, they should be retested between 24 and 28 weeks of gestation. Women of average risk should have testing undertaken at 24 to 28 weeks of gestation.

A fasting plasma glucose level >126 mg/dL (7.0 mmol/L) or a casual plasma glucose >200 mg/dL (11.1 mmol/L) meets the threshold for the diagnosis of diabetes. In the absence of unequivocal hyperglycemia, the diagnosis must be confirmed on a subsequent day. Confirmation of the diagnosis precludes the need for any glucose challenge. In the absence of this degree of hyperglycemia,

evaluation for GDM in women with average or high-risk characteristics should follow one of two approaches.

One-step approach.

Perform a diagnostic OGTT without prior plasma or serum glucose screening. The one-step approach may be cost-effective in high-risk patients or populations (e.g., some Native-American groups).

Two-step approach.

Perform an initial screening by measuring the plasma or serum glucose concentration 1 h after a 50-g oral glucose load (glucose challenge test [GCT]) and perform a diagnostic OGTT on that subset of women exceeding the glucose threshold value on the GCT. When the two-step approach is used, a glucose threshold value >140 mg/dL (7.8 mmol/L) identifies approximately 80% of women with GDM, and the yield is further increased to 90% by using a cutoff of >130 mg/dL (7.2 mmol/L).

With either approach, the diagnosis of GDM is based on an OGTT. Diagnostic criteria for the 100-g OGTT are derived from the original work of O'Sullivan and Mahan (1964) modified by Carpenter and Coustan (1982) and are shown in the top of Table 3 in the original guideline document. Alternatively, the diagnosis can be made using a 75-g glucose load and the glucose threshold values listed for fasting, 1 h, and 2 h (Table 3 in the original guideline, bottom); however, this test is not as well validated as the 100-g OGTT.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline is based largely on the reports of the Expert Committee on the Diagnosis and Classification of Diabetes (Diabetes Care 20:1183–1197, 1997, and Diabetes Care 26:3160–3167, 2003).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate diagnosis and classification of diabetes mellitus

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Evidence is only one component of clinical decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and above all, patient´s values and preferences, must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by the American Diabetes Association, may miss some nuances that are important in diabetes care. For example, while there is excellent evidence from clinical trials supporting the importance of achieving glycemic control, the optimal way to achieve this result is less clear. It is difficult to assess each component of such a complex intervention.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Diagnosis and classification of diabetes mellitus. Diabetes Care 2004 Jan;27(Suppl 1):S5-S10. [4 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Jan

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

American Diabetes Association (ADA)

GUIDELINE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from the American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus: Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 21(Suppl. 1):S5-S19, 1998.
- The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus: Follow-up report on the diagnosis of diabetes mellitus. Diabetes Care 26:3160-3167, 2003.

Print copies: Available from the American Diabetes Association (ADA), 1701 North Beauregard Street, Alexandria, VA 22311.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 25, 2004.

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Date Modified: 11/15/2004